DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

Cook Ireland Limited
Mr. Emmett Devereux
QA/RA Manager
O'Halloran Road
National Technology Park
Limerick
Ireland

JUL 27 2015

Re: K050578
Trade/Device Name: Duette™ Multi-Band Mucosectomy Device
Regulation Number: 21 CFR 876.4300
Regulation Name: Endoscopic electrosurgical unit and accessories
Regulatory Class: II
Product Code: KNS
Dated (Date on orig SE ltr): March 4, 2005
Received (Date on orig SE ltr): March 7, 2005

Dear Mr. Devereux,

This letter corrects our substantially equivalent letter of April 22, 2005.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be

found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Benjamin R. Fisher -S

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

K050578

510(k) Number (if known): K050578

Device Name: Duette™ Multi-Band Mucosectomy Device

Indications for Use:

The Duette™ Multi-Band Mucosectomy Device is intended for endoscopic mucosal resection in the upper gastrointestinal tract.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE-IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use Only ✓ OR Over-the-Counter ____
(Per 21 CFR § 801.109

Donald A. Lippman

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K050578

APR 2 2 2005

K050578

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510(k) Summary

SPONSOR:

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Date of Submission: March 4, 2005

Device:
Trade Name: **Duette™**
Cook Ireland Duette ™ Multi-Band Mucosectomy Device

Common/Usual Name: Mucosectomy Device/EMR Device

Class: Endoscope and Accessories. 21 CFR§ 876.1500, 78 KOG

Predicate Device: Olympus Distal Attachment (MH and MAJ models) for Endoscopic Mucosal Resection, K984358

Intended Use: The Duette™ Multi-Band Mucosectomy Device is intended for endoscopic mucosal resection in the upper gastrointestinal tract.

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Device Description:
The Duette ™ Multi-Band Mucosectomy Device has a ligation component consisting of a barrel with latex bands and a Ligator handle. This barrel is attached to the distal end of an endoscope and bands are deployed by actuating the handle. The barrel allows introduction of an electrosurgical snare for endoscopic therapies.

Comparison of Characteristics:
The subject device is similar with respect to intended use and/or design features to the predicate devices in terms of section 510(k) substantial equivalence.

Test Data:
Non-Clinical testing was performed on characteristics and operational functions of the Duette™ Multi-Band Mucosectomy Device deemed necessary to verify safety and performance.